RJA 2/17/22
JS 2/22/22

[redacted]

# P-18-0284

**Chemical Name:** [redacted]
**CASRN:** [redacted]

Updated on 10/5/2018 with Part A completion
Updated on 11/09/2018 with editorial changes

| ASSIGNMENTS | NAME | DATE |
|---|---|---|
| SAT Chair | William Irwin | 09-07-2018 |
| HH Hazard Assessor (A) | Sailesh Surapureddi | 09-07-2018 |
| HH Hazard QC Reviewer (A) | Iris Camacho | 09-23-2018 |
| HH Risk Assessor FOCUS (B) | Amy Benson | 09-20-2018 |
| HH Risk QC Reviewer (B) | Sailesh Surapureddi | 09-19-2018 |

| Human Health Report Status: | DATE COMPLETED |
|---|---|
| [redacted] | [redacted] |
| [redacted] | [redacted] |
| [redacted] | [redacted] |
| [redacted] | [redacted] |
| [redacted] | [redacted] |
| [redacted] | [redacted] |
| [redacted] | [redacted] |
| [redacted] | [redacted] |

[redacted]

# 1 HUMAN HEALTH SUMMARY

EPA estimated the human health hazard of this chemical substance based on its estimated physical/chemical properties, available PMN data, and by comparing it to structurally analogous chemical substances for which there is information on human health hazard, and other structural information. EPA concludes there is moderate concern for human health hazard for the chemical substance.

Based on the hazard determination and available quantitative and qualitative risk information, EPA concludes that there is risk for the PMN substance. The risk estimates for this chemical are for the intended conditions of use. Other conditions of use and their risks were not evaluated.

## 1.1 Hazard Summary

- Absorption through the skin is expected to be NIL to poor due to the slow PMN hydrolysis and p-chem properties. Absorption in the GI tract and lungs is expected to be poor to moderate with reaction based on p-chem properties
- Concerns for irritation and lung toxicity due to the reactivity of the chemical.
- Concern for developmental neurotoxicity; developmental, reproductive, blood toxicity; and neurotoxicity based on [redacted]
- Concerns for developmental toxicity for the branched alkane alcohol reaction products which may form branched chain fatty acids upon metabolism.

## 1.2 Risk Summary

### 1.2.1 Workers

**Quantitative risks**

**Inhalation:**
Risks were not identified for workers for developmental effects via inhalation of total particulates based on quantitative hazard data for the analogues [redacted] (MOE > 5,000; benchmark MOE = 1000) and [redacted] (MOE > 40,000; benchmark MOE = 66), respectively.

**Dermal:**
Risks were identified for workers for developmental via the dermal exposure based on quantitative hazard data for the analogue [redacted] (MOE = 36; benchmark MOE = 1000).

Risks were not identified for workers for developmental effects via the dermal route based on quantitative hazard data for the analogue [redacted] (MOE = 305; benchmark MOE = 66).

[redacted]

Irritation hazard to workers via the inhalation and dermal exposure andlung toxicity via the inhalation route based on the reactivity of the chemical were identified, but risk were not calculated due to lack of dose-reponse data for these hazards. Risks would be mitigated if exposures can be controlled by the use of appropriate PPE, including impervious gloves and a respirator.

### 1.2.2 General Population

Risks were not identified for the general population for developmental toxicity via drinking water intake and fish ingestion based on quantitative hazard data for analogues [redacted] (MOEs > 1 x $10^6$; benchmark MOEs = 66 and 1000).

Risks for the general population for inhalation were not assessed because air exposures were negligible (below modeling thresholds). .

### 1.2.3 Consumers

Risks to consumers were not evaluated because consumer use was not identified as a condition of use.

## 1.3 Potentially Useful Information:

### 1.3.1 Assumptions and Uncertainties

Absorption of the PMN is based on p-chem properties

There are no measured data on the PMN substance itself.

The reactivity of the PMN leads the hazard concerns

The metabolism of the PMN to release branched chain alkanes are assumed to be of developmental concern (these are longer chains and it is uncertain).

### 1.3.2 Potentially Useful Information

- 
- Toxicokinetics
- Developmental Toxicity

[redacted]

# 2 HUMAN HEALTH HAZARD- PART A

## 2.1 Chemistry Summary

| | | | | | |
|---|---|---|---|---|---|
| PMN: P-18-0284 | Submit | [redacted] | | Manu. | Import |
| Max. PV (KG): | [redacted] | Binding Option Marked: | | X | |
| MW: | [redacted] | % < 500 | | % <1000 | CASNO.: None |

| [redacted] | Prop. | Meas. | Est. |
|---|---|---|---|
| | MP | | |
| | BP | | >500 |
| | Pres. | | at 760 mm Hg |
| | VP | | <0.000001 |
| | S-H2O | | <0.000001/Rea |
| | log P | | 22.41 |

| Chemical Name | Analogues: |
|---|---|
| [redacted] | [redacted] |
| USE: | |
| [redacted] | |

## 2.1 SAT Summary

### 2.1.1 PMN Health Rating

H=2 Fate=P1B1, P2B1 Eco=1 T=2 and T2

### 2.1.2 SAT Key Words

Irr; Devel; Blood, Repro; Neuro; Lung

### 2.1.3 Absorption

Absorption through the skin is expected to be NIL to poor dermally due to the slow PMN hydrolysis and p-chem properties. Absorption in the GI tract and lungs is expected to be poor to moderate with reaction based on p-chem properties.

[redacted]

### 2.1.4 SAT Health Summary

There are concerns for neurotoxicity, developmental, blood and reproductive toxicity for the borate reaction product. There are concerns for irritation and lung toxicity due to the reactivity of the chemical. There are concerns for developmental toxicity for the branched alkane alcohol reaction products which may form branched chain fatty acids upon metabolism.

### 2.1.5 PMN Data (Study summary, POD)

Submitted with [redacted]

micronucleus assay; rat oral LD0 = 2000 mg/kg; rat dermal LD0 = 2000 mg/kg; mild eye irritation in rabbits, cleared by 72 hours; no skin irritation in rabbits; no skin sensitization in guinea pigs using the Buehler assay

### 2.1.6 Analogue Data (analogue, structure, study summary, POD)

Analogues: [redacted]

[redacted]

| CHEMISTRY REPORT ver. 04/98 | PAGE 5 | PMN: P-18-0284 |
|---|---|---|

**(38) ANALOGUES:**

| PMN or CAS No. | Chem. Name | Structure | TSCA Y/N |
|---|---|---|---|
| [redacted] | | | N |
| | | | N |
| | | | N |
| | | | N |
| | | | Y |
| | | | Y |
| | | | Y |
| | | | Y |

### 2.1.7 Other Information (SDS, structural alert or component of interest, basis, etc.)

**2.2 Potential Health Effects**

**Carcinogenicity Information:** Constituents are not classified as a carcinogen by IARC, OSHA, NTP or EPA.
**Skin Exposure:** May cause irritation with prolonged or repeated skin exposure
**Eye Exposure:** Contact with eyes may cause irritation.
**Inhalation:** May cause irritation to the respiratory tract.
**Swallowing:** May be harmful if swallowed

## Section 11: Toxicological Information

Not determined

### 2.1.8 Exposure Routes of Interest

| Route of Interest | |
|---|---|
| X | Inhalation: |

[redacted]

| | |
|---|---|
| X | Dermal: |
| X | Ingestion: |

## 2.2 Human Health Category (From US EPA 2010 document)

**Chemical Category:** [redacted] Compounds (for 1.2% of the compound)
**Chemical Category Health Concerns:** Reproductive, blood, neurotoxicity
**Category Testing Strategy:** OECD reproductive/developmental toxicity screen (OECD TG 421) with special attention to hematology**;** If positive, harmonized test guideline 870.3800 is recommended (2-generation reproductive toxicity study).

## 2.3 Point of Departure Selected and Basis

### 2.3.1 POD for [redacted] and compounds- [redacted]

**POD type: (NOAEL/LOAEL/NOAEC/LOAEC/Cancer Slope Factor/IUR/BMD) BMDL**
**POD Value:** 10.3 mg/kg/day
**POD Chemical:** [redacted]
**POD Route:** Oral
**POD Hazard Endpoint:** developmental toxicity
**POD Basis:** based on decreased fetal and offers protection for blood, neuro and developmental toxic effects
**POD Benchmark MOE:** 66 (A PBPK model was used for the IRIS RfD; therefore, the uncertainty factors differ from default values; the interspecies UF = 7.9 and the intraspecies UF = 6.3)
[redacted]

### 2.3.1 POD for [redacted] – Assume [redacted]

**POD type: LOAEL**
**POD Value:** 100 mg/kg-day
**POD Chemical:** [redacted]
**POD Route:** Oral
**POD Hazard Endpoint:** Developmental toxicity
**POD Basis:** Lowest POD for developmental effects for [redacted], based on skeletal variations
**POD Benchmark MOE:** 1000
**Reference:** EPA HPV document on [redacted], 2015

[redacted]

# 3 HUMAN HEALTH RISK (PART B)

## 3.1 USES and EXPOSURES

### 3.1.1 Uses

**USE:** [redacted]

**OTHER USES:** Analogues [redacted] Analogue [redacted]

### 3.1.2 Worker Exposure

#### 3.1.2.1 Inhalation

**Manufacturing**

Air releases are negligible (VP < 0.001 torr); Mist, aerosol, particulate generation is not expected during this operation.

**Coating fibrous substrate(non-volatile; class 1)**

Respirable particulates - PDR is [redacted] mg/day over [redacted] days/yr; [redacted] workers [redacted]

Total particulates – PDR is [redacted] mg/day over [redacted] days/year; [redacted] workers

**Extrusion: (non-volatile; Class I)**

Respirable particulates - PDR of [redacted] mg/day over [redacted] days/yr; [redacted] workers (unloading solid raw material))

Total particulates – PDR is [redacted] mg/day over [redacted] days/year; [redacted] workers

#### 3.1.2.2 Dermal

**Manufacturing**

High end exposure to [redacted]: PDR [redacted] mg/day over [redacted] days/yr; [redacted] workers

**Coating fibrous substrate**

High-end exposure to [redacted]: PDR of [redacted] mg/day over [redacted] days/yr; [redacted] workers [redacted]

High-end exposure to 1.48% solid: PDR of [redacted] mg/day over [redacted] days/yr; [redacted] workers [redacted]

**Extrusion**

High-end exposure to 1.48% solid: PDR of [redacted] mg/day over [redacted] days/yr; [redacted] workers [redacted]

[redacted]

### 3.1.3 General Population Exposure:

#### 3.1.3.1 Drinking Water

Adult: Drinking water ingestion with ADR as high as 5.19E-07 mg/kg/day

#### 3.1.3.2 Fish

Adult: Fish ingestion with ADR as high as 1.60E-05 mg/kg/day

#### 3.1.3.3 Air/Inhalation

Exposure from fugitive air release(s) and stack incineration were negligible (below modeling thresholds).

### 3.1.4 Consumer Exposure

No identified consumer exposures

[redacted]

## 3.2 RISK CALCULATIONS

### 3.2.1 Worker Calculations

Assume risk from [redacted] of PMN; adjusted for absorption only for the dermal route

**Worker Margin of Exposure (MOE) Calculations using Animal Oral POD and Engineering Report PDR: Risks from** [redacted]

| | Animal or Human | | | Human | | | | | | | Benchmark MOE | Endpo Type |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Exposure Route | POD mg/kg-day | POD Exposure Duration Days/Wk | POD Route % Absorp | Exposure mg/day Potential Dose Rate (PDR) | Exposure Duration Days/Wk | Exposure Route % Absorp | Body Weight kg | Exposure mg/kg-day | Structural Alert as % of PMN | Margin of Exposure MOE | 1000 | |
| Inhalation | 1.0E+02 | 7 | 100% | 2.2E+00 | 5 | 100% | 80 | 2.8E-02 | 98.8% | **5152.7** | | |
| Dermal | 1.0E+02 | 7 | 100% | 2.1E+03 | 5 | 15% | 80 | 2.6E+01 | 98.8% | **35.9874** | [redacted] | |

Assume risk from [redacted] of PMN; adjusted for absorption only for the dermal route

**Worker Margin of Exposure (MOE) Calculations using Animal Oral POD and Engineering Report PDR: Risks from** [redacted]

| | Animal or Human | | | Human | | | | | | | Benchmark MOE | Endpo Type |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Exposure Route | POD mg/kg-day | POD Exposure Duration Days/Wk | POD Route % Absorp | Exposure mg/day Potential Dose Rate (PDR) | Exposure Duration Days/Wk | Exposure Route % Absorp | Body Weight kg | Exposure mg/kg-day | Structural Alert as % of PMN | Margin of Exposure MOE | 66 | |
| Inhalation | 1.0E+01 | 7 | 100% | 2.2E+00 | 5 | 100% | 80 | 2.8E-02 | 1% | **43697.0** | | |
| Dermal | 1.0E+01 | 7 | 100% | 2.1E+03 | 5 | 15% | 80 | 2.6E+01 | 1% | **305.1852** | [redacted] | |

### 3.2.2 General Population Calculations

Assume risk from [redacted] of PMN; no adjustments for absorption

[redacted]

| General Population Margin of Exposure (MOE) Calculations using Animal Oral POD and Exposure Report ADR: Risks from [redacted] | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Animal or Human | | | Human | | | | | | Benchmark MOE | End Type |
| Exposure Route | POD mg/kg-day | POD Exposure Duration Days/Wk | POD Route % Absorp | Exposure mg/kg-day Acute Dose Rate (ADR) | Exposure Duration Days/Wk | Exposure Route % Absorp | Multiplier for Susceptible Subpopulations | Structural Alert as % of PMN | Margin of Exposure MOE | 1000 | |
| Drinking Water | 1.0E+02 | 7 | 100% | 5.2E-07 | 7 | 100% | 1.0 | 98.8% | **195,018,448.75** | [redacted] | |
| Drinking Water | 1.0E+02 | 7 | 100% | 5.2E-07 | 7 | 100% | 4.2 | 98.8% | **46,432,963.99** | | |
| Fish Ingestion | 1.0E+02 | 7 | 100% | 1.6E-05 | 7 | 100% | 1.0 | 98.8% | **6,325,910.93** | | |

| Genreral Population Margin of Exposure (MOE) Calculations using Animal Oral POD and Exposure Report ADR: Risks from [redacted] | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Animal or Human | | | Human | | | | | | Benchmark MOE | Endpo Type |
| Exposure Route | POD mg/kg-day | POD Exposure Duration Days/Wk | POD Route % Absorp | Exposure mg/kg-day Acute Dose Rate (ADR) | Exposure Duration Days/Wk | Exposure Route % Absorp | Multiplier for Susceptible Subpopulations | Structural Alert as % of PMN | Margin of Exposure MOE | | |
| Drinking Water | 1.03E+01 | 7 | 100% | 5.2E-07 | 7 | 100% | 1.0 | 1.2% | **1,653,821,451.51** | [redacted] | |
| Drinking Water | 1.03E+01 | 7 | 100% | 5.2E-07 | 7 | 100% | 4.2 | 1.2% | **393,767,012.26** | | |
| Fish Ingestion | 1.03E+01 | 7 | 100% | 1.6E-05 | 7 | 100% | 1.0 | 1.2% | **53,645,833.33** | | |

### 3.2.3 Consumer Calculations

Risks to consumers were not evaluated because consumer use was not identified as a condition of use.